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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,368	12/12/2003	Per Sauerberg	6594,200-US	2809
81848	7590	08/10/2009		
High Point Pharmaceuticals, Inc. 4170 Mendenhall Oaks Pkwy High Point, NC 27265			EXAMINER KEYS, ROSALYND ANN	
			ART UNIT	PAPER NUMBER
			1621	
			MAIL DATE	DELIVERY MODE
			08/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,368

Applicant(s)

SAUERBERG ET AL.

Examiner

Rosalynd Keys

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48, 53-66 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 is/are rejected.
- 7) ☒ Claim(s) 58, 59, and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims **withdrawn** from consideration are 5-8,12-15,23,25,29-31,35-37,53,55-57,60,62 and 70-73.

DETAILED ACTION

Status of Claims

1. Claims 1-48, 53-66, 69-73 are pending.

Claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 are rejected.

Claims 5-8, 12-15, 23, 25, 29-31, 35-37, 53, 55-57, 60, 62 and 70-73 are withdrawn from consideration.

Claims 58, 59, and 61 are objected.

Claims 49-52, 67, are 68 are cancelled.

Election/Restrictions

2. Claims 5-8, 12-15, 23, 25, 29-31, 35-37, 53, 55-57, 60, 62 and 70-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 20, 2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 are rejected under 35 U.S.C. 103(a) as obvious over Sauerberg et al. (WO 01/79150 A1) in view of Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al. (US 6,200,995 B1), for the reasons given in the previous office action, mailed November 7, 2008.

Response to Arguments

7. Applicant's arguments filed May 7, 2009 have been fully considered but they are not persuasive.

The Applicants submit that a patent applicant may be their own lexicographer and may define terms (within limits) as they may see fit. To that end, the Applicants searched the USPTO patent database and the evidence the Applicants found points toward the conclusion that, if Sauerberg wanted to include the polycyclic ring systems as instantly claimed in his invention, such groups would be specifically called out and not left in the phrase "and the like". More to the point, one of ordinary skill in the art would not conclude that the Y group of Sauerberg taught or fairly suggested the use of polycyclic ring systems as instantly claimed.

This submission is not persuasive because Sauerberg's generic use of the term "aryl" implies that instead of desiring to be their own lexicographer Sauerberg intends the term "aryl" to be given its ordinary and customary meaning. The ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, **and the state of the art.**" < Phillips v. AWH Corp., *415 F.3d at 1314<, 75 USPQ2d **>at 1327. Thus, contrary to the Applicants submission the use of the secondary references Pershadsingh et al. and De la Brouse-Elwood et al. to help determine what Sauerberg meant by the phrase "and the like" with respect to the meaning of aryl was not improper. Also unlike the patents 7,528,161 (directed to NF-

kappa inhibitors) and 7,528,448 (directed to thin film transistors) relied upon by the Applicants for a definition of the term "aryl" the Pershadsingh et al. and De la Brouse-Elwood et al. patents relied upon by the Examiner are directed to PPAR activators, like the compounds of Sauerberg and the instant compounds (see also Lou et al. (US 2002/0082263 A1), Houze et al. (US 2002/0120137 A1) and McGee et al. (US 2002/0169185 A1), also cited in the previous office action). Further, the Examiner also conducted a search of the patent database combining the term "aryl" with the term "Peroxisome Proliferator-Activated Receptors (PPAR)" and retrieved 2,967 hits. The Examiner reviewed the 12 most recent patents (7,557,123; 7,547,729; 7,544,835; 7,544,812; 7,544,809; 7,544,702; 7,538,135; 7,531,568; 7,528,160; 7,524,882; 7,517,884; and 7,507,832), wherein the compounds were disclosed as having PPAR action, and discovered that the term aryl was defined as phenyl, naphthyl and the like; not defined at all; defined as an aromatic cyclic group and specific examples thereof include phenyl, naphthyl, indacenyl and acenaphthylenyl; defined as including carbocyclic aromatic rings (e.g. phenyl), fused polycyclic aromatic ring systems (e.g. naphthyl and anthracenyl) and aromatic ring systems fused to carbocyclic non-aromatic ring systems (e.g., 1,2,3,4-tetrahydronaphthyl and benzodioxyl), with compounds expressly disclosed that have biphenyl rings; defined as meaning phenyl, naphthyl, biphenyl, tetrahydronaphthyl, alpha or beta-tetralonyl, indanyl or inda-1-onyl; defined as an aromatic substituent which can be single ring or multiple rings (up to three) which are fused together or linked covalently; defined as monocyclic or bicyclic aromatic hydrocarbon groups having 6 to 12 carbon atoms in the ring portion, such as phenyl,

naphthyl, tetrahydronaphthyl, biphenyl and diphenyl groups; defined as embracing aromatic radicals such as benzyl, phenyl, naphthyl, anthracenyl, phenanthryl, indanyl, annulenyl, azulenyl, tetrahydronaphthyl, and biphenyl; and defined as a carbocyclic aromatic system containing one, two or three rings wherein such rings may be attached together in a pendent manner or may be fused. It has been held that if more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings. ** See *e.g., < Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001). Based upon the state of the art, the use of the term aryl consistently includes a biphenyl ring. Thus, the term "aryl" in combination with the phrase "and the like" in Sauerberg may be construed to encompass divalent polycyclic ring systems within the claimed meaning.

The Applicants submit that Pershadsingh et al. teach away from the proposition that aryl means polycyclic ring systems as instantly claimed because Pershadsingh specifically recites aryl as a possible substituent on the previously defined aryl.

This argument is not persuasive the state of the art shows that aryl is known to be a substituent on an aryl group, including a biphenyl aryl (see for example 7,517,884 B2).

The Applicants submit that in reviewing the art, one skilled in the art would see, that a patent applicant typically specifically recites rings covalently bonded together when these ring systems are meant to be included in the definition of aryl.

This submission is not persuasive because a reference need not disclose what is well known in the art. In re MYERS, 161 USPQ 668 (CCPA 1969). Also there are patents wherein the definition for aryl includes a ring covalently bonded together, however the definition for aryl does not include the phrase biphenyl or rings covalently bonded together (see for example US 7,544,812, wherein aryl is defined as including carbocyclic aromatic rings (e.g. phenyl), fused polycyclic aromatic ring systems (e.g. naphthyl and anthracenyl) and aromatic ring systems fused to carbocyclic non-aromatic ring systems (e.g., 1,2,3,4-tetrahydronaphthyl and benzodioxyl). However the patent expressly discloses compounds wherein aryl means biphenyl (see for example General Example F in column 29; Example 10 in column 43; Example 39 in column 80; Example 216 in column 270; and Example 221 in column 273).

For the above reasons, the Examiner respectfully submits that the instant claims are prima facie obvious over Sauerberg et al. in view of Pershadsingh et al. and De la Brouse-Elwood et al.

Allowable Subject Matter

8. Claims 58, 59 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is (571)272-0639. The examiner can normally be reached on M & T 5:30 am-7 am & 9:30 am-4:30 pm; W-F 8:00 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROSALYND KEYS/
Primary Examiner, Art Unit 1621

November 3, 2008